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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,486	01/18/2002	Shi-Lung Lin	USP1941A-EI	7295

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EXAMINER	
CHONG, KIMBERLY	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/052,486	LIN, SHI-LUNG	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-116* is/are pending in the application.

4a) Of the above claim(s) *1-58,79-86,89-111* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *59-78,87,88 and 112-116* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ~~1/18/05~~ 2/26/02.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group IV, claims 59-78, 87, 88 and 112-116, in the reply filed on 11/05/2004 is acknowledged.

Claims 1-58, 79-86 and 89-111 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/05/2004.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claims 60-62 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 60 is drawn to a kit as defined in claim 59 and further comprises a machine to generate cDNA-aRNA hybrid constructs. Claim 61 is drawn to a kit as defined in claim 59 and further comprises generation of a cDNA-aRNA hybrid constructs from a temple of vectors by enzymatic methods. Claim 62 is drawn to a kit as defined in claim 61 wherein the cDNA-aRNA hybrid constructs are generated by RNA-polymerase cycling reactions.

Claims 60-62 are improper because they do not further limit the previous claim because the scope of the kits of claims 60-62 is identical to the scope of claim 59. Although the limitations of claims 60-62 include process steps by which the components of the kit are made, the process steps do not materially change the components of the kit and, therefore, the kits of claims 59-62 are identical.

Claim 59 is objected to because of the following informalities: Claim 59 has the statement "and so as to provide a specific gene silencing effect...". This statement is not proper English. This objection can be overcome if applicant amends the statement in the claim to "**to provide** a specific gene silencing effect...." Appropriate correction is required.

Claim 60 is objected to because of the following informalities: Claim 60 has the misspelled word "oilognucleotide". Appropriate correction is required.

Claim 74 is objected to because of the following informalities: Claim 74 has the statement "a composition comprises a plurality of DNA-RNA hybrids...." This objection can be

overcome if applicant amends the statement in the claim to "a composition comprising a plurality of DNA-RNA hybrids...." Appropriate correction is required.

Claim 77 is objected to because of the following informalities: Claim 77 has the statement "wherein said organisms are mammalian origins." The statement is not proper English. The objection can be overcome if applicant amend the statement in the claim to "wherein said organisms **of** mammalian origin." Appropriate correction is required.

Claims 87 and 88 are objected to because of the following informalities: The instant claims are objected to as dependent on a non-elected claim. This objection can be overcome if all the limitations of claim 85 are incorporated into the instant claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 74-78, 87-88, and 113-116 are rejected under 35 U.S.C. 102(b) as being anticipated by Baracchini et al. (U.S. Patent Number 5,801,154).

Claims 74-78, 87-88 and 113-116 of the instant application are drawn to a composition comprising a plurality of DNA-RNA hybrids capable of inducing sequence specific gene silencing in cells or organisms.

Baracchini et al. discloses cells transfected with a plurality antisense DNA oligonucleotides. These DNA oligos hybridize to a plurality of mRNA molecules, forming DNA-RNA hybrids which induce sequence-specific gene silencing in cells and organisms comprising these cells. These cells are encompassed in the scope of a composition comprising a plurality of DNA-RNA hybrids capable of inducing sequence-specific gene silencing or knockout effects in cells and organisms.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 59-78 and 87-88 are rejected under 35 U.S.C. 102(a) as being anticipated by Lin et al. (Biochem. and Biophys. Res. Comm. 2001, 281:639-644).

Claims 59-73 of the instant application are drawn to a kit for inducing gene silencing effects comprising a cDNA-aRNA hybrid construct and a transfection reagent. Claims 74-78, 87 and 88 are drawn to a composition comprising a plurality of DNA-RNA hybrids capable of inducing sequence specific gene silencing in cells or organisms.

Lin et al. discloses a cDNA-aRNA hybrid construct and transfection reagents and the cDNA-aRNA hybrid is capable of inducing sequence specific gene silencing in cells or organism

(see page 640 materials and methods). Further, the word "kit" in the instant claims does not materially change the composition of a cDNA-RNA hybrid and therefore absent evidence to the contrary, claims 59-78 and 87-88 are anticipated by Lin et al.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 59-78, 87-88 and 112-116 are rejected under 35 U.S.C. 102(e) as being anticipated by Lin et al. (US 2002/0137709 A1).

Claims 59-73 of the instant application are drawn to a kit for inducing gene silencing effects comprising a cDNA-aRNA hybrid construct and a transfection reagent. Claims 74-78, 87 and 88 are drawn to a composition comprising a plurality of DNA-RNA hybrids capable of inducing sequence specific gene silencing in cells or organisms. Claim 112 further limits claim 59 by stating the cDNA-aRNA hybrid comprises at least one nucleotide analog. Claims 113-116 further limit claim 74 by stating the DNA-RNA hybrid comprises at least one nucleotide, the DNA molecule comprises at least one ribonucleotide or its analog and the RNA molecule comprises at least one deoxyribonucleotide.

Lin et al. discloses an mRNA-cDNA hybrid and chemical or liposomal transfection reagents that when introduced into cells or organisms are capable of inducing gene silencing

effects (see paragraph 0020). Lin et al. further discloses mRNA-cDNA hybrids with nucleotide analogs (see paragraphs 0020 and 0076). Further, the word "kit" in the instant claims does not materially change the composition of a cDNA-RNA hybrid and therefore absent evidence to the contrary, claims 59-78, 87-88 and 112-116 are anticipated by Lin et al.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 59 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the term "homologous" in claims 59 and 64 is a relative term which renders the claim indefinite. The term "homologous" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "homologous" in claims 59 and 64 does not provide one of ordinary skill in the art a standard on how to determine how homologous or to what degree of homology to the intracellular messenger RNA sequences the cDNA-aRNA hybrid construct must be to be considered "homologous" rather than a completely unrelated molecule.

Claims 60 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 60 and 61 each recite the limitation wherein the claimed kit "further comprising the generation of said cDNA-aRNA hybrids constructs by...." This limitation appears to add a method step and it is unclear if a kit or a method step is actually being claimed.

Claim 65 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the term "partially homologous" in claim 65 is a relative term which renders the claim indefinite. The term "partially homologous" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "partially homologous" in claim 65 does not provide one of ordinary skill in the art the standard on how to determine how partially homologous or to what degree of partial homology to the intracellular messenger RNA sequences the cDNA-aRNA hybrid construct must be to be considered "partially homologous" rather than a completely unrelated molecule.

Claim 75 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the term "high vertebrate origins" in claim 75 is a relative term which renders the claim indefinite. The term " high vertebrate origins " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. One of ordinary skill in the art would not know which cells of which organisms are encompassed in the claims because the metes and bounds of the term "high vertebrate origins" is unclear. There is no art recognized limit for what vertebrates constitute "high". Claim 76 depends from claim 75 but is not subject to this particular rejection because the cells are defined as being from a group selected from mouse, rat, rabbit, canine, chicken and human and, therefore, the metes and bounds of the claim in clear.

Claim 76 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 76 is directed to alternative limitations; however, the claim does not utilize proper alternative language because of the recitation "comprising". Specifically claim 76 states "said cells are selected from a group of cultured tissue cells comprising mouse, rat, rabbit, canine and human cells." MPEP 2173.05(h) states in part:

> "Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of ...."

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Therefore the term "comprising" does not provide one of ordinary skill in the art the scope or boundaries of the groups of animals from which the tissue cells are selected.

Claim 78 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 78 is directed to alternative limitations; however, the claim does not utilize proper alternative language because of the recitation "comprising". Specifically claim 78 states "said organisms are selected from a group of animals comprising mouse, rat, rabbit, canine and human beings." MPEP 2173.05(h) states in part:

> "Alternative expression are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of ...."

Therefore the term "comprising" does not provide one of ordinary skill in the art the scope or boundaries of the groups of animals from which the organisms are selected.

Claims 87 and 88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 87 and 88 recite the phrases "derived from...." It is unclear if the claimed cell line is made using the process of claim 74 or if the cell line utilizes the process of claim 74.

Further, claims 87 and 88 recite the phrase "utilizes a process as defined in claim 85." Claim 85 recites a process as defined in claim 74 but it does not appear an actual process in made in claim 74.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached at 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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